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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/307,956	05/10/1999	JAMES R. SCHNEIDER	13394	5537

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EXAMINER	
ISABELLA, DAVID J	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/307,956	SCHNEIDER, JAMES R.	
	Examiner	Art Unit	
	DAVID J. ISABELLA	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-49* is/are pending in the application.

4a) Of the above claim(s) *48 and 49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Status of the Claims

This application was revived from abandoned status with a filing of an RCE on 2/1/2005. Amendments to the claims were filed along with the RCE. Claims 1-26 were cancelled. Claims 27-37 were previously presented and claim 27 was amended. Claims 38-49 were newly added. Claims 38-47 are directed to a preserved vessel and claims 48-49 are directed to a method for implanting a vessel.

Election/Restrictions

Newly submitted claims 48 and 49 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: method does not require the specific product of claims 27-47. The product of claims 27-47 may be used in a different method than that of claims 48 and 49.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 48 and 49 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27-34,38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pratt (Publications Laryngoscope 96: 1986; 29th Ann. Meeting of Amer Society for Head and Neck Surgery: 1987) in view of Dardik et al.

The publications to Pratt discloses the use of freezed-dried microarterial allografts that have reduced immune response when implanted. In each of the publication, Pratt suggests that free dried placental vessels should be explored as microarterial allografts. Pratt, on page 628, discloses that a similar study by Chow, using freezed dried placental heterograft/allograft vessels as vascular substitute. It is clear from the studies by Pratt and Chow that freeze dried tissues prevent immune response.

Dardik, et al teaches that placental and umbilical tissues have been used as a source for microarterial vessels for reconstructive surgery. In 1976, the current skill in the art was to chemically modify the vessels from the umbilical cord by tanning to remove surface antigens. It has been found that the tanning chemicals themselves modifies the surface of the treated vessels so as to, inherently, cause immune response. In light of the teachings of Dardik, et al, to use the vessels derived from placental and/or umbilical tissues as a source of microarterial allografts that can be

freezed-dried to yield a reconstructive allograft that exhibits low immune response would have been obvious to one with ordinary skill in the art at the time of the invention thereof.

The limitations of the dependent claims are fully met by combination of Pratt and Dardik, et al..

Claims 35-37,45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pratt and Dardik as applied to claims 27 and 38, respectively, and further in view of Lau, et al and Chin.

Dardik, et al is silent as to the use of polyamides however Dardik, et al suggest the broad use of polyesters as the material for stent construction. Lau, et al teaches the specific use of polyamides to reinforce umbilical derived tissues. To use nylon as a stent for reinforcing the tissue of Pratt would have been obvious from the combined teachings of Dardik, et al and Lau, et al to provide a vessel with more support in vivo.

Chin teaches the use of bifurcated stent graft derived from umbilical source. To use stents in bifurcating vessels would have been obvious from the teachings of Chin as a means for providing additional vessel support in vivo.

Response to Arguments

Applicant's arguments filed 2/1/2005 and Declaration under Rule 1.32 have been fully considered but they are not persuasive. The articles of Pratt clearly disclose the

freeze-drying of the grafts. While not entirely successful, the process was known at the time of the invention.

Applicant argues that Pratt discloses studies in rabbits using freeze-dried arterial allografts made from femoral or brachial arteries. While examiner agrees with the basis of the study, examiner directs applicant's attention to page 628 of Laryngoscope 96, disclosing that Chow studied freeze-dired placental yessels as heterografts/allografts and found that heterografts stimulates a stronger immune reaction than an allograft.

terial autografts in the rabbit femoral artery.[4] A similar study by Chow compared freeze-dried microarterial allografts to autografts in the rat.[5] He reported 84% patency of the freeze-dried allografts at 1 to 3 months. Chow more recently studied freeze-dried human placental vessels as heterografts in the rabbit and reported a 55% patency rate at 3 months.[6] Although freeze-drying only retarded the process of host immune reaction to a heterograft in Chow's study, it seemed to prevent an immune response to the allograft in this study. It would appear that a heterograft, as expected, stimulates a stronger immune reaction than an allograft and, therefore, would not make as good a vascular substitute. A good topic for further investigation would be the study of freeze-dried human placental vessels used as microarterial allografts. Success with such an investigation would provide a readily available source of vascular grafts without the inconvenience and additional morbidity associated with harvesting autogenous veins.

Examiner's reliance on Dardik, et al is simply to establish that use of vessels derived from placental and umbilical tissues have been used as a source for microarterial graft. While Dardik et al uses chemical treatment to reduce antigenic properties of the isolated vessels, Pratt clearly established, prior to the invention herein that lyophilization of vessels reduces the vessel's immune response especially as used as an allograft. Examiner is not suggesting to substitute or use the chemical method of Dardik in combination with lyophilization for as a method for treating the vessel to

reduce immunogenicity combination of the prior art as applied teach/suggest all the claim limitations.

Applicant argued that the Ofiice has failed to establish a prima facie case of obviousness for failure to meet at least one of the three required criteria set out above - namely, reasonable expectation of success. Examiner respectfully, disagrees with applicant's assertion. It is clear that lyophilization of vascular vessels including those derived from the placenta have achieved success in reduction of immunogenicity. Examiner contends that at the time of the invention thereof, it has been clearly demonstrated by Pratt and Chow (and others) that lyophilization is successful in reducing the immune response to treated vascular vessels, especially as used as an allograft. Moreover, Chow study indicated that lyophilized placental vessels were successful as a source for microarterial graft exhibiting reduced immunogenicity. Examiner maintains that the prior art points to a reasonable expectation of success in using lyophilized umbilical vessels as a source for microarterial graft. Morevoer, the

With respect to applicants arguments to Lau and Chin, this argument is moot. Whether the stent remains in place or is removed, the combination is still rendered obvious as argued by the examiner. The claim is directed to the positive combination of the preserved vessel and the stent.

With respect to applicant's Declaration under Rule 1.32, the declaration is not commensurate with the scope of the invention as claimed.

The Schneider Declaration provides evidence that preserved vessels prepared by freeze-drying placental or umbilical cord vessels maintain sufficient integrity for use as grafts, and further can withstand pressure similar to that found in an adult. While applicant argues that freeze drying may destroy the integrity of the vessels, no evidence was presented supporting that freeze drying placental vessels differs from freeze drying umbilical vessels. According to Chow and admitted by Pratt, success was reasonably expected with umbilical vessels that have undergone lyophilization.

Applicant's declaration with respect to utilization of the vessels in situations with increased pressure is not well taken.

Applicant's statement:

Similarly, there was no reasonable expectation that freeze-dried vessels could be used in an adult graft and withstand at least twice or more the blood pressure than that to which the fresh tissue is subjected in nature.

The claims are devoid of such language and limitations and thus applicant's arguments pertaining to the manner in which the grafts are used are moot. Moreover, the statement is incorrect, in that, a study by Chow appears to indicate that the graft would have sufficient integrity and immunological properties after grafting.

Applicant's assertion that the studies above demonstrate thatumbilical cord and placental vessels can be preserved by freeze-drying according to the invention and maintain sufficient integrity to be useful as grafts in a human adult has been noted, however the statement and corresponding arguments are not commensurate with the scope of the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
6/7/2006